DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS MAIL

MAY 4 2001

Mr. Mohammed J. Choudhry
Owner and Managing Director
Puretone, Ltd.
9-10 Henley Business Park
Trident Close, Medway City Estate
Rochester, Kent, ME2 4FR, ENGLAND

Dear Mr. Choudhry:

We are writing to you because on March 5/7, 2001, an investigator from the Food and Drug Administration (FDA) inspected your facility and determined that your firm manufactures non-programmable Tinnitus maskers and non-programmable air-conduction hearing aids that are exported to the United States.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System (QS) regulation found in Title 21, Part 820 of the U.S. Code of Federal Regulations (CFR). The following deviations were identified:

1. 21 CFR 820.20 (3)(i)

Your procedures for conducting quality audits were not complete. 21 CFR 820.20 (3)(i) requires that management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part. For example, Observation 1A on the FD 483 indicates that your firm's "Internal Quality Audits" Procedure (QP04) specifies "each element of the quality system (by clause number) is audited at least twice per year". However, there is no mention of auditing against any other requirements beyond the twenty ISO clauses. (e.g. the Quality System regulations) Also Observation 1C indicates that your firm's Quality Audit procedures do not specify that all organizational functions, processes, facility controls, etc. subject to the ISO clauses (and Quality System requirements) be audited. There are three locations where production processing occurs. There is no specified requirement that all three areas be audited.

Our initial inspection in 1998 found that your firm had a Quality System in place and while you were certified to ISO 9001:1994 and EN46001:1996, you were unfamiliar with the FDA requirements of 21 CFR 820. A copy of FDA's requirements was provided to you at that time. This item was not included on the previous FD 483, but was included in the discussion with management.

Your response to the current FD 483 indicates that you will revise your quality system to comply with the FDA requirements as well as your own ISO 9001, BS EN 46001 and MD 93/42 EEC requirements. Your firm's auditing responsibilities were enhanced to include reference to requirements other than ISO 9001 (QM1/20 page 34). This revised page indicates "relevant Food & Drug Administration regulations are audited formally to monitor the effective functioning of each aspect of the intended controls." This response needs to be more specific.

You also indicated that you redefined your production to "high light custom man'f-solder ass'y & SMT (revised audit program)". Please clarify what you mean by this. This response still doesn't appear to address observation 1C regarding the three manufacturing areas.

2. 21 CFR 820.22

A manufacturer is required to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Observation 1B on the FD 483 indicates that your firm's quality audit procedures do not specify that the adequacy of quality system requirements be determined during the audit (e.g. determine not only whether procedures exist and are complied with, but whether the procedures are adequate to begin with.)

Your firm's response indicated that you have enhanced your responsibilities to include an assessment of the procedure's relevance (QP2 section 4 page 13). A review of this procedure indicates that prior to commencement of an audit check, the auditor is to check to ensure the adequacy of the procedure/process against company requirements, standards and relevant regulations. This response appears to be adequate, but will need to be verified that your firm is following it during the next inspection.

3. 21 CFR 820.25 (b)

Each manufacturer is required to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities and that such training is documented. Observation 1D indicates that your firm's Quality Audit procedures do not specify specific measurable auditor qualification requirements (e.g. classroom and practical training requirements, etc.).

Your firm's response indicated that you have expanded your auditor training requirements (QP2 section 4 page 12 and training record). QP2 indicates that auditors will be trained on a external audit course and when they have received their certificate they will be allocated various audits to complete under the guidance of other more experienced auditors in the company to monitor their compliance on audit requirements and controls. When the General Manager confirms them as acceptable internal auditors they will then be allocated various audit reports to complete within the next pre-planned audits. Details of their skills training will be recorded on the training record held for each employee. This response appears satisfactorily and will be verified during the next inspection.

4. 21 CFR 820.20 (a)

Management with executive responsibility is required to establish policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization. Observation 2 on the FD 483 indicates that management with executive responsibility has not ensured that the quality policy has been fully implemented and maintained at all levels of the organization. Specifically, five of five employees interviewed on 7 March 2001 were unfamiliar with the quality policy and/or did not know where the quality policy was located. Additionally, "ISO 9001 Quality Awareness Training" does not include a specific review of the quality policy.

Your firm's response to the FD 483 indicates that the Quality policy has been revised and issued to your employees. A large copy is now displayed in the canteen area and a copy will be given to all employees at their quality awareness training. A copy of the revised procedure was provided. This response appears adequate, but will need to be verified during the next inspection.

5. 21 CFR 820.30

Each manufacturer of any class III or class II devices and specific class I devices (tracheobronchial suction catheters, surgeon's gloves, protective restraints, radionclide system applicator(manual) and radionuclide teletherapy devices) is required to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. Your Tinnitus masker device is a Class II device. Observation 3 on the FD 483 indicates that your procedures to control the design process were not complete. Specifically, your firm's design control procedures do not specify that the development of new or revised labeling and packaging designs be controlled using your design control procedures.

Your response indicates that design procedures have been revised so that all new designs will consider the labeling and the packaging as part of the design for a given device. You provided flow charts and a copy of page 14 of QM1/9 Design Control. One of the flow charts has a block that says Labeling and Packaging will be included in the design process. You also indicated that design forms were modified. This is not an adequate response. No specific procedures were provided (i.e.- for Design and development planning, Design Inputs, Design output, Design review, Design verification, Design validation, Design transfer and Design changes) and no indication of re-training of employees was indicated. No copies of the modified design forms were provided.

6. 21 CFR 820.100(a)(1)

Each manufacturer is required to establish and maintain procedures for implementing corrective and preventive actions. The procedures need to include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Observation 4 on the FD 483 indicates that corrective and preventive action procedures (CAPA) addressing the analysis of quality data to identify existing and potential causes of nonconforming product or other quality problems were not complete. Specifically, procedures have not been established to capture and analyze quality data generated from service and repair activities.

The initial inspection of your firm also listed on the FD 483 that your CAPA procedures did not assure that data collected from service/repair records could be evaluated to identify existing or potential causes of non-conforming products or other quality problems. Your firm was advised that you needed to do both corrective and preventive procedures at that time.

Your firm's response to the current FD 483 indicates that statistical data management will be revised over the next four months. This will involve writing reports from the data that you currently collect on devices returned within a short period of time, to allow you to look for trends and fluctuations in model types-assemblers-sequential serial numbers, etc. This is not an adequate response. You still haven't adequately addressed looking at the data from your service and repair activities.

7. 21 CFR 803.17

User facilities and manufacturers are required to develop, maintain, and implement written MDR procedures. Observation 5 of the FD 483 indicates that written medical device reporting (MDR) procedures have not been developed, maintained or implemented. Your firm has a Vigilance Reporting system that appears to comply with the European Union Vigilance requirements, however, it does not address FDA's MDR requirements. The CDRH web-site was reviewed with you during the inspection and the investigator explained where you could find the information necessary to develop, maintain and implement an MDR procedure.

Your response indicates that you will notify the "MDA" of any adverse incidents where serious injury or death has occurred. You plan to extend your vigilance system to include devices sold to the U.S. where any MDA reports will also trigger an MDR to the FDA. You enclosed a flow chart showing how this changed your current system. This response is not adequate. You still do not seem to understand all of the MDR requirements. We are providing attachments concerning the MDR regulations from our web-site that should provide you with the background for our regulations. Please submit a more complete procedure to address these requirements.

8. 21 CFR 820.181

The Device Master Record (DMR) for each type of device shall include, or refer to the location of, the following information: device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications and installation, maintenance and servicing procedures and methods. Observation 6 of the FD 483 indicates that your firm's DMR (Technical Construction files (TCF)) do not include or refer to the location of all device specifications. Specifically, technical construction files do not include or reference the location of quality assurance procedures, specifications and equipment used or packaging and labeling specifications. According to exhibit 12A, the TCF should contain the necessary information contained within a DMR, however the TCF for the Tinnitus Masker did not contain or refer to the location of the specified information. The requirements of 21 CFR 820.181 were discussed with you at the close of the inspection.

Your response indicates that the TCF are maintained for each device under the Medical device directive. A general Index has been added to the TCF to indicate the contents and their location. This is also supposed to be a cross-reference of MDA and FDA terminology. You provided a copy of "Technical Construction File Build (DMR-Device Master Record)". This is supposed to be a list of the parts that make up a TCF/DMR and their locations. This response is not adequate. This does not specifically address the deficiency. Please provide the revised TCF for the Tinnitus Masker.

9. 21 CFR 820.184(e)

The Device History Record (DHR) must include or refer to the location of the primary identification label and labeling used for each production unit. Observation 7 on the FD 483 indicates that the DHR do not include or refer to the location of primary identification labels and labeling for each device. (Specifically, DHR relating for job numbers 804 and 805.)

This observation is similar to observation 2 on the FDA 483 from your previous EI that stated that final device test results and labels are not routinely retained as part of the DHR.

Your response indicates that your packing instructions have been rewritten for export goods to add a note requiring a copy product label to be placed on their production list. This response is not adequate because it doesn't address the specific observation dealing with job numbers 804 and 805. Please clarify what your production list refers to.

Our investigator also discussed several observations that were not documented on the FD 483. As mentioned above, 21 CFR 820.25 requires that training be documented. According to your representative, on-the-job training (OTJ) is still the primary training method used at this firm. However OTJ is not described within your firm's Training Procedure or training records. This observation was also included on the FD 483 for the previous EI.

Your narrative response did not address this observation but, a one page form was attached that is titled "Puretone Ltd- Employee Training Records". It lists numerous skills and a check-off square to indicate whether this skill is required and a block to indicate when the training was completed. You need to address this issue in greater detail to clarify what this form represents.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and it's implementing regulations. The specific violations noted in this letter and in the FD 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality systems. You are responsible for investigating and determining the causes of the violations identified by FDA. When violations involve systems problems, you must promptly initiate permanent corrective action.

We acknowledge that Puretone Ltd. submitted to this office a response to our investigator's observations noted on the FD 483. We have reviewed your response and have concluded that it is inadequate because it has not completely addressed all of the concerns on the FD 483.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Give the serious nature of the violations that have been identified, all devices manufactured at Puretone Ltd. may be detained without physical examination upon entry into the United States until these violations are corrected.

Your response should be sent to Ms. Mary-Lou Davis of the Dental, ENT and Ophthalmic Devices Branch at the above address. If you have any questions concerning this letter, you may call her at (301) 594-4613, extension 127 or FAX at (301) 594-4638.

Sincerely yours,

James L Wash for

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health

Attachments: MDR regulations